DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 17 2007

Re: Fosrenol
Docket No.: 2005E-0248

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,968,976, filed by Shire International Licensing, B.V., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Fosrenol (lanthanum carbonate hydrate), the human drug product claimed by the patent.

The total length of the regulatory review period for Fosrenol (lanthanum carbonate hydrate) is 2,449 days. Of this time, 1,538 days occurred during the testing phase and 911 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 13, 1998.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 13, 1998.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 30, 2002.

   FDA has verified the applicant's claim that the new drug application (NDA) for Fosrenol (lanthanum carbonate hydrate) (NDA 21-468) was initially submitted on April 30, 2002.

3. The date the application was approved: October 26, 2004.

   FDA has verified the applicant's claim that NDA 21-468 was approved on October 26, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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